

## DETAILED ACTION

**Claims 1-7 are pending.**

### ***Claim Rejections - 35 USC § 101***

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

the claimed invention is directed to non-statutory subject matter. The claims 1-5 are "use claims" and it does encompass statutory subject matter.

3. Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinica/Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that *yeast* sp strain KCTC 0959B is required to practice the claimed invention. As such the biological material must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the *yeast* sp strain KCTC 0959B.

The process disclosed in the specification does not appear to be repeatable, it is not clear that the invention will work with commonly available material and it is not apparent if the biological materials considered necessary to make and use the invention is both known and readily available to the public. A person skilled in the art could not make or use the invention defined in and commensurate with the claims without access to the specific biological material. It is noted that Applicant has deposited biological material but there no indication in the specification as to public availability. Therefore, a deposit at a recognized depository may be made to overcome this rejection.

If the deposit is made under the terms of the Budapest Treaty, then a statement, affidavit or declaration by Applicant, or by an attorney of record over his or her signature and registration number, or by someone in a position to corroborate the facts of the deposit, that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit is a non-Budapest Treaty deposit, then in order to certify that the deposit meets the criteria set forth in 37 CFR §1.801-1.809 and MPEP §2402-2411.05, a statement, affidavit or declaration by Applicant, by an attorney of record over his or

her signature and registration number, or by someone in a position to corroborate the facts of the deposit would satisfy the requirements herein by stating and providing that:

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) provide evidence of the test of the viability of the biological material at the time of deposit (see 37 CFR §1.807);

(e) stating that the deposit will be replaced if it should ever become inviable; and

(f) the specification must state a date of deposit, deposit number, name and address of the depository, and a taxonomic description of the deposit.

It is noted that on page 9 of the instant specification, Applicant has satisfied most of the required components of (f); however, Applicant failed to provide the address of the depository. Applicant is required to provide the address of the depository as specified by MPEP §1.805(b).

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**2. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jamas et al. (US Patent 5250436) ('436), Jamas et al. (US Patent 6020324) ('324), Jung K et al. (J.Vet.Med 2004) in view of Lee et al. ( Biosci.Biotechnol. Biochem, 2001).**

'436 describes a two step process of extraction of glucan particles from yeast. The first step involves the extraction and purification of whole glucan particles from the yeast or fungal cell walls. The second step involves whole glucan treated with chemical or enzymatic treatment. The purpose of the second step is to alter the ratio of  $\beta$ -(1-6)/ $\beta$ -(1-3) linkages.  $\beta$ -(1-6) linkage is reduced by treating whole glucan with acetic acid or with a  $\beta$ -(1-6) specific glucanase enzyme (col 3, ln 22-52). The amount of  $\beta$ -(1-3) linked glucan can be decreased by treating the whole glucan particles with a  $\beta$ -(1-3) specific glucanase enzyme. '436 further teaches that yeast is preferably a strain of *Saccharomyces cerevisiae*, but any strain of yeast can be used (col 2, ln 24-25).

'436 does not teach the use of  $\beta$ -glucan as a dietary or pharmaceutical composition and using for treating influenza or gastroenteritis coronavirus in mammals.

'324 teaches the use of  $\beta$ -glucan as dietary supplement can be administered orally, or enterally. The form in which the glucan will be administered (e.g., powder, tablet, capsule, suspension, solution, emulsion (col 6, ln 16-20). The use of glucan in diarrhea helps by providing very high water holding capacity and high dietary fiber content and can be obtained from any yeast strain (col 4, ln 26-28). For example, the following strains, and mutants or variants derived from them, will yield whole  $\beta$ -glucans:

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*Saccharomyces cerevisiae*, *Saccharomyces delbrueckii*, *Saccharomyces rosei*,  
*Saccharomyces microellipsodes*, *Saccharomyces carlsbergensis*,  
*Schizosaccharomyces pombe*, *Kluyveromyces lactis*, *Kluyveromyces fragilis*,  
*Kluyveromyces polysporus*, *Candida albicans*, *Candida cloacae*, *Candida tropicalis*,  
*Candida utilis*, *Hansenula wingei*, *Hansenula arni*, *Hansenula henricii* and *Hansenula americana* (col 4, ln 29-37). The process of extraction is described by incorporation from S. Jamas et al. in U.S. Pat. No. 4,810,646 (col 4, ln 3) and mentions that the  $\beta$ -glucan product obtained from this process is typically about 96-99% pure; and, since the cell wall structure is intact, it also has a significantly higher water holding capacity than glucans extracted using traditional methods, which lack the intact three-dimensional structure (col 4, ln 39-45). Glucan has hydrophilic water absorbing agent makes them valuable as dietary additives acting as a fiber supplement and/or a stool bulking agent that enhances bowel function (col 5, ln 64-67). Enzymatic modification of whole glucan can allow a range of digestability (from about 15 to about 70% metabolizable glucose) and water holding capacity (from about 3 to about 12 ml/g of dry material) (col 6, ln 1-3).

'324 does not teach the use of  $\beta$ -glucan for treating influenza or pharmaceutical compositions.

Jung K et al. teaches that  $\beta$ -glucan was orally administered to pigs, with and without SIV infection (pg 73, ln 4-8). Jung K et al. further teaches that macrophages play an important role in the generation of specific and non-specific immunity (pg 75, ln 20-21). Jung K et al. also further teach that immunomodulation induced by *S.cerevisiae*  $\beta$ -glucan enhanced this specific response against the influenza virus (pg 75, second

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para last lines). Jung K et al. further concludes that potential application of  $\beta$ -glucan as treatment agent in influenza virus infection (pg 75, discussion last lines).

Lee et al. teaches that cell wall of yeast, *Saccharomyces cerevisiae*, contains  $\beta$ -D-glucan, chitin and mannoprotein (pg 837, col 2, ln 1-3).  $\beta$ -glucan is known to possess antimicrobial and antitumor activities by enhancing the host immune function, and activates macrophages, neutrophils and NK cells by binding to the  $\beta$ -glucan receptor on these cells (pg 837, col 2, second para).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the '436 to obtain  $\beta$ -glucan from any strain of yeast and combine it with '364, Jung K et al. and Lee et al. to incorporate it in dietary or pharmaceutical preparations.  $\beta$ -glucan enhances the macrophage cell count which in turn increases immunity and can be combined with any formulations that are directed or targeted to macrophage cells such as viral influenza. '324 also teaches the benefit of adding the  $\beta$ -glucan is helpful in diarrhea as it holds the water which is beneficial to prevent dehydration in patients with diarrhea. The applicant has not specially described the mode of action of  $\beta$ -glucan to prevent transmissible gastroenteritis coronavirus and it can be concluded that the mechanism of treatment would be the same mechanism as mentioned in '324, Lee et al. and Jung K et al. to treat any gastrointestinal infection.  $\beta$ -glucan would stimulate the immunity and help retain water in gastrointestinal infections induced by virus or bacteria. The applicant has also not established the specific benefit of a particular strain of yeast that has been claimed so based on the

references cited any type of yeast strain can be used to extract a specific type of  $\beta$ -glucan for therapeutic purposes.

One would be motivated to make this combination of the said references to benefit from knowledge of using various strains of yeast for extracting  $\beta$ -glucan with enzymatic hydrolysis and obtaining a pharmaceutical or nutritional grade product to use for diarrhea or any infectious diseases. Given the state of the art as evidenced by the teachings of the cited references and there would have been a reasonable expectation of success in combining the teachings of the cited references to obtain a natural product from yeast as  $\beta$ -glucan for treating diarrhea or boost immune function via increasing the macrophage counts.

### ***Conclusion***

No claims are allowed. All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GEETA KADAMBI whose telephone number is (571) 270-5234. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on 571-272-0867 or Cecelia Tsang at 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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